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TOWNSEND AND TOWNSEND AND CREW, LLP
TWO EMBARCADERO CENTER
EIGHTH FLOOR
SAN FRANCISCO, CA 94111-3834

EXAMINER	
THANGAVELU, KANDASAMY	
ART UNIT	**PAPER NUMBER**
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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/823,213	DUNLAVEY, MICHAEL R.	
	Examiner	Art Unit	
	Kandasamy Thangavelu	2123	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *15 November 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-3,5,6,9-12,14-17 and 19-25* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3,5,6,9-12,14-17 and 19-25* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. This communication is in response to the Applicants' amendment dated on November 15, 2004. Claims 1, 5, 6, 9, 14 and 19 were amended. Claims 4, 7-8, 13 and 18 were deleted. Claims 20-25 were added. Claims 1-3, 5, 6, 9-12, 14-17 and 19-25 of the application are pending. This office action is made non-final.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains.

3. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

4. Claims 1-3, 5, 6, 10 and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Herren et al.** (U.S. Patent 6,108,635) in view of **Hoskins et al.** (U.S. Patent 6,268,853), and further in view of **Bleicher et al.** (U.S. Patent 6,820,235), **Heughebaert et al.** (U.S. Patent 6,408,431) and **Whitehill et al.** (U.S. Patent 6,708,329).

4.1 **Herren et al.** teaches Integrated disease information system. Specifically, as per claim 1, **Herren et al.** teaches a system for clinical trial simulation (Abstract, L1-8 and L17-30; Fig. 3; CL4, L21-31; CL14, L15-20; CL14, L36-37); comprising:

the interface configured to receive information that describes a trial for a clinical trial simulation (Abstract, L1-8 and L17-30; Fig. 3; CL4, L21-28; CL14, L23-30); and

the controller configured to run the executable program (CL4, L21-31; CL14, L15-20).

Herren et al. does not expressly teach an interface having a fixed form module and a free form module. **Hoskins et al.** teaches an interface having a fixed form module and a free form module (CL116, L58-60; CL117, L23-28), because the preferred fixed form template language allows different kinds of module specifications that can be used to accommodate different circumstances (CL116, L58-60). It would have been obvious to one of ordinary skill in the art at the time of Applicant's invention to modify the system of **Herren et al.** with the system of **Hoskins et al.** that included an interface having a fixed form module and a free form module. The artisan would have been motivated because the preferred fixed form template language would allow different kinds of module specifications that can be used to accommodate different circumstances.

Herren et al. does not expressly teach a trial protocol comprising a plurality of schedules for a clinical trial simulation; and the controller configured to run the executable program according to a time queue. **Bleicher et al.** teaches a trial protocol comprising a plurality of schedules for a clinical trial simulation; and the controller configured to run the executable program according to a time queue (CL2, L8-14), because the protocol specifies the exact timing and nature of the interventions and the measurements to be performed on each patient in the form of a series of events (CL2, L8-11). It would have been obvious to one of ordinary skill in the art at the time of Applicant's invention to modify the system of **Herren et al.** with the system of **Bleicher et al.** that included a trial protocol comprising a plurality of schedules for a clinical trial simulation; and the controller configured to run the executable program according to a time queue. The artisan would have been motivated because the protocol would specify the exact timing and nature of the interventions and the measurements to be performed on each patient in the form of a series of events.

Herren et al. does not expressly teach a translator having a protocol parser and a code generator, the protocol parser configured to parse the trial protocol, the code generator configured to generate source code in a general purpose programming language. **Heughebaert et al.** teaches a translator having a protocol parser and a code generator, the protocol parser configured to parse the trial protocol, the code generator configured to generate source code in a general purpose programming language (Fig. 3; CL3, L30-53), because the code generator takes information from the specification file and produces a source code file that can be used by the compiler to produce executable code (CL1, L14-16; CL3, L9-12). It would have been obvious to one of ordinary skill in the art at the time of Applicant's invention to modify the system of

Herren et al. with the system of **Heughebaert et al.** that included a translator having a protocol parser and a code generator, the protocol parser configured to parse the trial protocol, the code generator configured to generate source code in a general purpose programming language. The artisan would have been motivated because the code generator would take information from the specification file and produce a source code file that could be used by the compiler to produce executable code.

Herren et al. does not expressly teach a compiler having a code parser and a machine code generator, the compiler configured to compile the generated source code into an executable program. **Heughebaert et al.** teaches a compiler having a code parser and a machine code generator, the compiler configured to compile the generated source code into an executable program (Fig. 3; CL3, L30-53; CL3, L9-12), because as per **Herren et al.** that allows the computer based system to receive the biological parameters, disease measures, patient characteristics etc.; perform simulation of clinical trials; and output results of analyses to support identification of targets and interventions, design clinical trials analysis of the interventions and present disease progression information (CL4, L21-31; CL14, L15-20). It would have been obvious to one of ordinary skill in the art at the time of Applicant's invention to modify the system of **Herren et al.** with the system of **Heughebaert et al.** that included a compiler having a code parser and a machine code generator, the compiler configured to compile the generated source code into an executable program. The artisan would have been motivated because that would allow the computer based system to receive the biological parameters, disease measures, patient characteristics etc.; perform simulation of clinical trials; and output results of analyses to

support identification of targets and interventions, design clinical trials analysis of the interventions and present disease progression information.

Herren et al. does not expressly teach a controller communicatively coupled with the interface, the translator, and the compiler. **Hoskins et al.** teaches a controller communicatively coupled with the interface, the translator, and the compiler (CL7, L49-52; CL109, L15-18), because that allows the controller to integrate the simulation system design, simulation and implementation (CL109, L15-17). It would have been obvious to one of ordinary skill in the art at the time of Applicant's invention to modify the system of **Herren et al.** with the system of **Hoskins et al.** that included a controller communicatively coupled with the interface, the translator, and the compiler. The artisan would have been motivated because that would allow the controller to integrate the simulation system design, simulation and implementation.

Herren et al. does not expressly teach the executable program comprising a plurality of programmable state machines; and each state machine corresponds to a one of the plurality of schedules. **Whitehill et al.** teaches the executable program comprising a plurality of programmable state machines; and each state machine corresponds to a one of the plurality of schedules (CL5, L4-11), because the functionality of the elements are indicated in the form of state machines that utilize the software modules to simulate the functions (CL5, L4-7). It would have been obvious to one of ordinary skill in the art at the time of Applicant's invention to modify the system of **Herren et al.** with the system of **Whitehill et al.** that included the executable program comprising a plurality of programmable state machines; and each state machine corresponds to a one of the plurality of schedules. The artisan would have been

motivated because the functionality of the elements would be indicated in the form of state machines that utilized the software modules to simulate the functions.

4.2 As per claim 2, **Herren et al., Hoskins et al., Bleicher et al., Heughebaert et al.** and **Whitehill et al.** teach the system of claim 1. **Herren et al.** does not expressly teach that the fixed form module is configured to receive trail protocol information conforming to a structured format. **Hoskins et al.** teaches that the fixed form module is configured to receive trail protocol information conforming to a structured format (CL116, L58-60; CL117, L23-28), because the preferred fixed form template language allows different kinds of module specifications that can be used to accommodate different circumstances (CL116, L58-60). It would have been obvious to one of ordinary skill in the art at the time of Applicant's invention to modify the system of **Herren et al.** with the system of **Hoskins et al.** that included the fixed form module being configured to receive trail protocol information conforming to a structured format. The artisan would have been motivated because the preferred fixed form template language would allow different kinds of module specifications that can be used to accommodate different circumstances.

4.3 As per claim 3, **Herren et al., Hoskins et al., Bleicher et al., Heughebaert et al.** and **Whitehill et al.** teach the system of claim 2. **Herren et al.** does not expressly teach the free form module is configured to receive trial protocol information conforming to a trial design language. **Heughebaert et al.** teaches the free form module is configured to receive trial protocol information conforming to a trial design language (Fig. 3; CL3, L30-53), because that

allows specification of the trial protocol information containing the distinctive features of the code to be generated with the aid of the trial design (specification) language (CL3, L32-34). It would have been obvious to one of ordinary skill in the art at the time of Applicant's invention to modify the system of **Herren et al.** with the system of **Heughebaert et al.** that included the free form module being configured to receive trial protocol information conforming to a trial design language. The artisan would have been motivated because that would allow specification of the trial protocol information containing the distinctive features of the code to be generated with the aid of the trial design (specification) language.

Per claim 5: **Herren et al.** teaches that the plurality of schedules comprises a dosing schedule (Fig. 12b).

4.4 As per claim 10 **Herren et al., Bleicher et al., Heughebaert et al.** and **Whitehill et al.** teach the method of claim 9. **Herren et al.** does not expressly teach receiving trial protocol information that conforms to a structured format. **Hoskins et al.** teaches receiving trial protocol information that conforms to a structured format (CL116, L58-60; CL117, L23-28), because the preferred fixed form template language allows different kinds of module specifications that can be used to accommodate different circumstances (CL116, L58-60). It would have been obvious to one of ordinary skill in the art at the time of Applicant's invention to modify the method of **Herren et al.** with the method of **Hoskins et al.** that included receiving trial protocol information that conforms to a structured format. The artisan would have been motivated

because the preferred fixed form template language would allow different kinds of module specifications that can be used to accommodate different circumstances.

Herren et al. does not expressly teach receiving trial protocol information that conforms to a trial design language. **Heughebaert et al.** teaches receiving trial protocol information that conforms to a trial design language (Fig. 3; CL3, L30-53), because that allows specification of the trial protocol information containing the distinctive features of the code to be generated with the aid of the trial design (specification) language (CL3, L32-34). It would have been obvious to one of ordinary skill in the art at the time of Applicant's invention to modify the method of **Herren et al.** with the method of **Heughebaert et al.** that included receiving trial protocol information that conforms to a trial design language. The artisan would have been motivated because that would allow specification of the trial protocol information containing the distinctive features of the code to be generated with the aid of the trial design (specification) language.

4.5 As per Claim 15, it is rejected based on the same reasoning as Claim 10, supra. Claim 15 is computer readable medium claim reciting the same limitations as Claim 10, as taught throughout by **Herren et al., Hoskins et al., Bleicher et al., Heughebaert et al.** and **Whitehill et al.**

5. Claim 6 is rejected under 35 U.S.C. 103(a) as being unpatentable over **Herren et al.** (U.S. Patent 6,108,635) in view of **Hoskins et al.** (U.S. Patent 6,268,853), and further in view of **Bleicher et al.** (U.S. Patent 6,820,235), **Heughebaert et al.** (U.S. Patent 6,408,431), **Whitehill et al.** (U.S. Patent 6,708,329) and **Fink et al.** (U.S. Patent 5,808,918).

5.1 As per claim 6, **Herren et al., Hoskins et al., Bleicher et al., Heughebaert et al.** and **Whitehill et al.** teach the system of claim 1. **Herren et al.** does not expressly teach the plurality of schedules comprises an observation schedule. **Fink et al.** teaches the plurality of schedules comprises an observation schedule (CL13, L21-25), because that allows the computer based system to simulate various combinations of schedules to predict and successfully alter clinical outcomes manifested as signs and symptoms of the disease (CL3, L32-34). It would have been obvious to one of ordinary skill in the art at the time of Applicant's invention to modify the system of **Herren et al.** with the system of **Fink et al.** that included the plurality of schedules comprising an observation schedule. The artisan would have been motivated because that would allow the computer based system to simulate various combinations of schedules to predict and successfully alter clinical outcomes manifested as signs and symptoms of the disease.

6. Claims 9, 11, 14, 16, 19, 22 and 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Herren et al.** (U.S. Patent 6,108,635) in view of **Bleicher et al.** (U.S. Patent 6,820,235), and further in view of **Heughebaert et al.** (U.S. Patent 6,408,431), **Whitehill et al.** (U.S. Patent 6,708,329).

6.1 As per claim 9, **Herren et al.** teaches a method for clinical trial simulation (Abstract, L1-8 and L17-30; Fig. 3; CL4, L21-31; CL14, L15-20; CL14, L36-37); comprising:

receiving information that describes a trial for a clinical trial simulation (Abstract, L1-8 and L17-30; Fig. 3; CL4, L21-28; CL14, L23-30); and

executing the program as part of the clinical trial simulation (CL4, L21-31; CL14, L15-20).

Herren et al. does not expressly teach receiving trial protocol information that describes a clinical trial simulation; arranging the trial protocol information into a plurality of schedules; and executing the program according to a time queue. **Bleicher et al.** teaches receiving trial protocol information that describes a clinical trial simulation; arranging the trial protocol information into a plurality of schedules; and executing the program according to a time queue (CL2, L8-14), because the protocol specifies the exact timing and nature of the interventions and the measurements to be performed on each patient in the form of a series of events (CL2, L8-11). It would have been obvious to one of ordinary skill in the art at the time of Applicant's invention to modify the method of **Herren et al.** with the method of **Bleicher et al.** that included receiving trial protocol information that describes a clinical trial simulation; arranging the trial protocol information into a plurality of schedules; and executing the program according to a time queue. The artisan would have been motivated because the protocol would specify the exact timing and nature of the interventions and the measurements to be performed on each patient in the form of a series of events.

Herren et al. does not expressly teach translating the plurality of schedules into a general purpose, high level programming language. **Heughebaert et al.** teaches translating the plurality of schedules into a general purpose, high level programming language (Fig. 3; CL3, L30-53), because the code generator takes information from the specification file and produces a source code file that can be used by the compiler to produce executable code (CL1, L14-16; CL3, L9-

12). It would have been obvious to one of ordinary skill in the art at the time of Applicant's invention to modify the method of **Herren et al.** with the method of **Heughebaert et al.** that included translating the plurality of schedules into a general purpose, high level programming language. The artisan would have been motivated because the code generator would take information from the specification file and produce a source code file that could be used by the compiler to produce executable code.

Herren et al. does not expressly teach compiling the translated plurality of schedules into an executable program. **Heughebaert et al.** teaches compiling the translated plurality of schedules into an executable program (Fig. 3; CL3, L30-53; CL3, L9-12), because as per **Herren et al.** that allows the computer based system to receive the biological parameters, disease measures, patient characteristics etc.; perform simulation of clinical trials; and output results of analyses to support identification of targets and interventions, design clinical trials analysis of the interventions and present disease progression information (CL4, L21-31; CL14, L15-20). It would have been obvious to one of ordinary skill in the art at the time of Applicant's invention to modify the method of **Herren et al.** with the method of **Heughebaert et al.** that included compiling the translated plurality of schedules into an executable program. The artisan would have been motivated because that would allow the computer based system to receive the biological parameters, disease measures, patient characteristics etc.; perform simulation of clinical trials; and output results of analyses to support identification of targets and interventions, design clinical trials analysis of the interventions and present disease progression information.

Herren et al. does not expressly teach the executable program comprising a plurality of state machines; and each state machine corresponds to a one of the plurality of schedules.

Whitehill et al. teaches the executable program comprising a plurality of state machines; and each state machine corresponds to a one of the plurality of schedules (CL5, L4-11), because the functionality of the elements are indicated in the form of state machines that utilize the software modules to simulate the functions (CL5, L4-7). It would have been obvious to one of ordinary skill in the art at the time of Applicant's invention to modify the method of **Herren et al.** with the method of **Whitehill et al.** that included the executable program comprising a plurality of state machines; and each state machine corresponds to a one of the plurality of schedules. The artisan would have been motivated because the functionality of the elements would be indicated in the form of state machines that utilized the software modules to simulate the functions.

Per claim 11: **Herren et al.** teaches that the plurality of schedules comprises a dosing schedule (Fig. 12b).

6.2 As per Claims 14 and 16, these are rejected based on the same reasoning as Claims 9 and 11, supra. Claims 14 and 16 are computer readable medium claims reciting the same limitations as Claims 9 and 11, as taught throughout by **Herren et al., Bleicher et al., Heughebaert et al.** and **Whitehill et al.**

6.3 As per claim 19, **Herren et al.** teaches a system comprising a microprocessor, a persistent storage area, a volatile storage area and a communication means, the system including an execution area configured to simulate a clinical trial (Abstract, L1-8 and L17-30; Fig. 3; CL4, L21-31; CL14, L15-20; CL14, L36-37); comprising:

receiving information that describes a trial for a clinical trial simulation (Abstract, L1-8 and L17-30; Fig. 3; CL4, L21-28; CL14, L23-30); and

executing the program as part of the clinical trial simulation (CL4, L21-31; CL14, L15-20).

Herren et al. does not expressly teach receiving trial protocol information that describes a clinical trial simulation; arranging the trial protocol information into a plurality of schedules; and executing the program according to a time queue. **Bleicher et al.** teaches receiving trial protocol information that describes a clinical trial simulation; arranging the trial protocol information into a plurality of schedules; and executing the program according to a time queue (CL2, L8-14), because the protocol specifies the exact timing and nature of the interventions and the measurements to be performed on each patient in the form of a series of events (CL2, L8-11). It would have been obvious to one of ordinary skill in the art at the time of Applicant's invention to modify the system of **Herren et al.** with the system of **Bleicher et al.** that included receiving trial protocol information that describes a clinical trial simulation; arranging the trial protocol information into a plurality of schedules; and executing the program according to a time queue. The artisan would have been motivated because the protocol would specify the exact timing and nature of the interventions and the measurements to be performed on each patient in the form of a series of events.

Herren et al. does not expressly teach translating the plurality of schedules into a general purpose, high level programming language. **Heughebaert et al.** teaches translating the plurality of schedules into a general purpose, high level programming language (Fig. 3; CL3, L30-53),

because the code generator takes information from the specification file and produces a source code file that can be used by the compiler to produce executable code (CL1, L14-16; CL3, L9-12). It would have been obvious to one of ordinary skill in the art at the time of Applicant's invention to modify the system of **Herren et al.** with the system of **Heughebaert et al.** that included translating the plurality of schedules into a general purpose, high level programming language. The artisan would have been motivated because the code generator would take information from the specification file and produce a source code file that could be used by the compiler to produce executable code.

Herren et al. does not expressly teach compiling the translated plurality of schedules into an executable program. **Heughebaert et al.** teaches compiling the translated plurality of schedules into an executable program (Fig. 3; CL3, L30-53; CL3, L9-12), because as per **Herren et al.** that allows the computer based system to receive the biological parameters, disease measures, patient characteristics etc.; perform simulation of clinical trials; and output results of analyses to support identification of targets and interventions, design clinical trials analysis of the interventions and present disease progression information (CL4, L21-31; CL14, L15-20). It would have been obvious to one of ordinary skill in the art at the time of Applicant's invention to modify the system of **Herren et al.** with the system of **Heughebaert et al.** that included compiling the translated plurality of schedules into an executable program. The artisan would have been motivated because that would allow the computer based system to receive the biological parameters, disease measures, patient characteristics etc.; perform simulation of clinical trials; and output results of analyses to support identification of targets and interventions, design clinical trials analysis of the interventions and present disease progression information.

Herren et al. does not expressly teach the executable program comprising a plurality of state machines; and each state machine corresponds to a one of the plurality of schedules. **Whitehill et al.** teaches the executable program comprising a plurality of state machines; and each state machine corresponds to a one of the plurality of schedules (CL5, L4-11), because the functionality of the elements are indicated in the form of state machines that utilize the software modules to simulate the functions (CL5, L4-7). It would have been obvious to one of ordinary skill in the art at the time of Applicant's invention to modify the system of **Herren et al.** with the system of **Whitehill et al.** that included the executable program comprising a plurality of state machines; and each state machine corresponds to a one of the plurality of schedules. The artisan would have been motivated because the functionality of the elements would be indicated in the form of state machines that utilized the software modules to simulate the functions.

6.4 As per claim 22 **Herren et al., Bleicher et al., Heughebaert et al.** and **Whitehill et al.** teach the method of claim 9. **Herren et al.** does not expressly teach that the trial protocol information is arranged into a plurality of schedules according to a syntax and a structure of the trial protocol information. **Bleicher et al.** teaches that the trial protocol information is arranged into a plurality of schedules according to a syntax and a structure of the trial protocol information (Abstract, L1-14; CL2, L8-14), because the protocol specifies the exact timing and nature of the interventions and the measurements to be performed on each patient in the form of a series of events (CL2, L8-11); and the process can be used for managing clinical trial data during trial (Abstract, L1-14). It would have been obvious to one of ordinary skill in the art at the time of Applicant's invention to modify the method of **Herren et al.** with the method of **Bleicher et al.**

that included the trial protocol information being arranged into a plurality of schedules according to a syntax and a structure of the trial protocol information. The artisan would have been motivated because the protocol would specify the exact timing and nature of the interventions and the measurements to be performed on each patient in the form of a series of events; and the process can be used for managing clinical trial data during trial.

6.5 As per Claim 24, it is rejected based on the same reasoning as Claim 22, supra. Claim 24 is a computer readable medium claims reciting the same limitations as Claim 22, as taught throughout by **Herren et al., Bleicher et al., Heughebaert et al.** and **Whitehill et al.**

7. Claims 12 and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Herren et al.** (U.S. Patent 6,108,635) in view of **Bleicher et al.** (U.S. Patent 6,820,235), and further in view of **Heughebaert et al.** (U.S. Patent 6,408,431), **Whitehill et al.** (U.S. Patent 6,708,329) and **Fink et al.** (U.S. Patent 5,808,918).

7.1 As per claim 12, **Herren et al., Bleicher et al., Heughebaert et al.** and **Whitehill et al.** teach the method of claim 9. **Herren et al.** does not expressly teach the plurality of schedules comprises an observation schedule. **Fink et al.** teaches the plurality of schedules comprises an observation schedule (CL13, L21-25), because that allows the computer based system to simulate various combinations of schedules to predict and successfully alter clinical outcomes manifested as signs and symptoms of the disease (CL3, L32-34). It would have been obvious to one of ordinary skill in the art at the time of Applicant's invention to modify the method of

Herren et al. with the method of **Fink et al.** that included the plurality of schedules comprising an observation schedule. The artisan would have been motivated because that would allow the computer based system to simulate various combinations of schedules to predict and successfully alter clinical outcomes manifested as signs and symptoms of the disease.

7.2 As per Claim 17, it is rejected based on the same reasoning as Claim 12, supra. Claim 17 is a computer readable medium claims reciting the same limitations as Claim 12, as taught throughout by **Herren et al., Bleicher et al., Heughebaert et al., Whitehill et al.** and **Fink et al.**

8. Claims 20 and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Herren et al.** (U.S. Patent 6,108,635) in view of **Hoskins et al.** (U.S. Patent 6,268,853), and further in view of **Bleicher et al.** (U.S. Patent 6,820,235), **Heughebaert et al.** (U.S. Patent 6,408,431), **Whitehill et al.** (U.S. Patent 6,708,329) and **Arimilli et al.** (U.S. Patent 6,823,471).

8.1 As per claims 20 and 21, **Herren et al., Hoskins et al., Bleicher et al., Heughebaert et al.** and **Whitehill et al.** teach the system of claim 1. **Herren et al.** does not expressly teach that the translator operates according to a syntax and a structure of the trial protocol; and the protocol parser is configured to determine a syntax and a structure of the trial protocol, to convert the trial protocol into an intermediate format, and to pass the intermediate format to the code generator. **Arimilli et al.** teaches that the translator operates according to a syntax and a structure of the trial protocol; and the protocol parser is configured to determine a syntax and a structure of the

trial protocol, to convert the trial protocol into an intermediate format, and to pass the intermediate format to the code generator (Fig. 5; CL5, L12-34), because that allows verifying that the protocols parsed by the parser are legal and meaningful in the context (CL5, L23-24). It would have been obvious to one of ordinary skill in the art at the time of Applicant's invention to modify the system of **Herren et al.** with the system of **Arimilli et al.** that included the translator operating according to a syntax and a structure of the trial protocol; and the protocol parser being configured to determine a syntax and a structure of the trial protocol, to convert the trial protocol into an intermediate format, and to pass the intermediate format to the code generator. The artisan would have been motivated because that would allow verifying that the protocols parsed by the parser are legal and meaningful in the context.

9. Claims 23 and 25 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Herren et al.** (U.S. Patent 6,108,635) in view of **Bleicher et al.** (U.S. Patent 6,820,235), and further in view of **Heughebaert et al.** (U.S. Patent 6,408,431), **Whitehill et al.** (U.S. Patent 6,708,329) and **Arimilli et al.** (U.S. Patent 6,823,471).

9.1 As per claim 23, **Herren et al., Bleicher et al., Heughebaert et al.** and **Whitehill et al.** teach the method of claim 22. **Herren et al.** does not expressly teach that the trial protocol information is analyzed to determine the syntax and structure. **Arimilli et al.** teaches that the trial protocol information is analyzed to determine the syntax and structure (Fig. 5; CL5, L12-34), because that allows verifying that the protocols parsed by the parser are legal and meaningful in the context (CL5, L23-24). It would have been obvious to one of ordinary skill in

the art at the time of Applicant's invention to modify the system of **Herren et al.** with the system of **Arimilli et al.** that included the trial protocol information being analyzed to determine the syntax and structure. The artisan would have been motivated because that would allow verifying that the protocols parsed by the parser are legal and meaningful in the context.

9.2 As per Claim 25, it is rejected based on the same reasoning as Claim 23, supra. Claim 25 is a computer readable medium claims reciting the same limitations as Claim 23, as taught throughout by **Herren et al., Bleicher et al., Heughebaert et al., Whitehill et al.** and **Arimilli et al.**

Response to Arguments

10.1 As per the applicants' argument that "this use of the term "protocol" by the Lin Patent, bears no relation to the "clinical trial protocol" of the instant application; neither the above-cited passage, nor any other portion of the Lin Patent, teaches or suggests receiving a drug development clinical trial protocol comprising a plurality of schedules, and then generating source code corresponding to a plurality of state machines from the trial protocol ... like the Lin Patent, the Fink Patent teaches only a general proposition: a schedule for administering medication is one parameter of a clinical trial; the Fink Patent says nothing to teach, or even to suggest, a method or system wherein a clinical trial protocol comprising a plurality of schedules is received, and source code is generated therefrom corresponding to a plurality of state

machines", the examiner has used the **Bleicher et al.** reference which teaches clinical trial data management.

Bleicher et al. teaches a trial protocol comprising a plurality of schedules for a clinical trial simulation; and the controller configured to run the executable program according to a time queue (CL2, L8-14), because the protocol specifies the exact timing and nature of the interventions and the measurements to be performed on each patient in the form of a series of events (CL2, L8-11).

10.2 As per the applicants' argument that "it cannot reasonably be asserted that the Lin Patent is analogous art to the instant application; while both ostensibly relate to the simulation of complex systems, a reference describing simulation of differential global positioning systems would hardly have commended itself to the attention of an inventor grappling with problems of simulating behavior of a pharmaceutical entity in a clinical trial; accordingly, there can be no question that the Lin Patent lies far outside the realm of the instant application", the examiner has used a new reference, **Bleicher et al.** reference which teaches clinical trial data management.

Conclusion

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dr. Kandasamy Thangavelu whose telephone number is 571-272-3717. The examiner can normally be reached on Monday through Friday from 8:00 AM to 5:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Teska, can be reached on 571-272-3716. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-305-9600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

K. Thangavelu
Art Unit 2123
February 8, 2005